REMARKS

Claims 1, 3, 8, 9, 12 and 14 have been amended.

Claim 14 has been amended to correct typographical errors.

Claims 10-11 and 15-20 have been canceled.

The specification has been amended to identify parent applications by serial number as well as patent number. Priority to these documents has been claimed previously; the amendment simply provides the serial number for each of those documents in addition to the patent number previously provided.

35 U.S.C. §102

MPEP 2131 quotes Verdegaal Brothers v. Union Oil of California, 814 F.2d 628, 631 (Fed. Cir. 1987) for the legal standard of anticipation: "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (emphasis added).

Claims 1-2

Amended claim 1 claims "[a]n integrated anastomosis tool for forming an opening in a target vessel and connecting a graft vessel to the target vessel, the device comprising: a substantially hollow chamber and an introducer positioned at a distal end of the chamber and having a lumen open to the chamber, the introducer configured to substantially seal against the target vessel, whereby the chamber substantially maintains hemostasis; a cutting device movably attached to the tool body and configured to form the opening in the target vessel; and a graft vessel attachment device movably attached to the tool body and configured to connect the graft vessel to the target vessel; wherein the cutting device is movable both longitudinally and transversely, and wherein the cutting device is movable to a position within the chamber

after forming the opening in the target vessel."

In contrast, U.S. Pat. No. 6,605,098 to Nobis et. al. ("Nobis") does not expressly or inherently describe each and every element of amended claim 1. Nobis discloses a seal 633 that is an elastomer sheet "which returns to its shape after withdrawal of the punch 600." (Nobis; col. 9, lines 36-43; Figure 18). The punch of Nobis is withdrawn proximally to a location proximal to the seal 633 after making an opening in a vessel, after which the cartridge 200 passes distally through the seal 633. (Nobis; col. 9, lines 31-51; Figures 14b, 18). To the extent that the seal prevents liquid in the vessel from entering the tool, the seal 633 necessarily traps that liquid in a location distal to the seal 633, because the vessel is located distal to the seal 633. Thus, the punch of Nobis is withdrawn out of a volume of the tool distal to the seal 633 in which liquid is trapped.

In contrast, claim 1 requires a chamber that substantially maintains hemostasis, and requires the cutting device to be "movable to a position within the chamber after forming the opening in the target vessel." (*e.g.*, paragraph 0049; Figures 5-6). To the extent that Nobis discloses any such "chamber," it is the volume of Nobis distal to the seal 633 – the volume from which the punch 600 is completely withdrawn in the proximal direction after forming the opening in the vessel.

Thus, Nobis does not expressly or inherently describe each and every element claimed in claim 1, and claim 1 is believed to be in condition for allowance. Claim 2 depends from claim 1, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

Claims 3-8

Claim 3 has been amended to claim "[a] device for forming an opening in a target vessel and delivering an implantable anastomosis device to connect a graft vessel to the target

vessel, the device comprising: a tool body having a lumen; a cutting device configured to form the opening in the target vessel, the cutting device being movable at least partially within the lumen; and a graft vessel attachment device movable at least partially within the lumen for delivering the implantable anastomosis device to the target vessel to connect the graft vessel to the target vessel; wherein the cutting device is movable away from the axial centerline of the lumen."

The lineage of this application is set forth in the first sentence of the application, which has been amended to identify the parents of this application by serial number as well as by patent number. Amended claim 3 is fully supported by the grandparent of this application, U.S. Pat. No. 6,371,964 (serial no. 09/440,263). The claim limitation "a tool body having a lumen" is disclosed by, for example, col. 14, lines 40-59 and Figures 27-34. The claim limitation "a cutting device configured to form the opening in the target vessel, the cutting device being movable at least partially within the lumen" is disclosed by, for example, col. 14, lines 40-47 and Figures 27-34. The claim limitation "a graft vessel attachment device movable at least partially within the lumen for delivering the implantable anastomosis device to the target vessel to connect the graft vessel to the target vessel" is disclosed by, for example, col. 14, lines 61-63 and Figures 35-37. The claim limitation "wherein the cutting device is movable away from the axial centerline of the lumen" is disclosed by, for example, col. 14, lines 48-46 and Figures 30-33.

The grandparent to this application, U.S. Pat. No. 6,371,964 was filed on November 15, 1999, almost two years prior to the filing date of Nobis. Claim 3 is fully supported by the disclosure in that grandparent. Thus, under MPEP 706.02(V)(B), Nobis is not prior art to amended claim 3. As a result, claim 3 is believed to be in condition for allowance. Claims 4-8 depend directly or indirectly from claim 8, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

Claims 9, 21

Amended claim 9 claims "An anastomosis tool for forming an opening in a target vessel and connecting a graft vessel to the target vessel, the device comprising: a tool body having an aperture at a distal end thereof; a cutting device positioned at least partially in the tool body and having a distal end configured to form the opening in the target vessel, at least the distal end of the cutting device movable through the aperture; and a graft vessel attachment device positioned at least partially in the tool body and having a distal end configured to connect the graft vessel to the target vessel, at least the distal end of the graft vessel attachment device movable through the aperture; wherein the cutting device is movable linearly along a first direction and the graft vessel attachment device is movable linearly along a second direction substantially non-parallel to the first direction, wherein both the first and second directions are angled relative to the longitudinal direction."

Referring to Figure 13B, the cutting device moves along a first line non-parallel to a second line along which the graft vessel attachment device moves, and each of those lines is angled relative to the longitudinal direction. In contrast, Nobis fails to disclose linear motion of the cartridge 200 and the punch 600 in two different directions, each angled relative to the longitudinal direction. As a result, claim 9 is believed to be in condition for allowance. Claim 21 depends from claim 9, and is thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

Claims 12-14

Amended claim 12 claims "[a] device for forming an opening in a target vessel, delivering an implantable anastomosis device to the target vessel, and connecting a graft vessel to the target vessel, the device comprising: a cutting device configured to form the

opening in the target vessel; a graft vessel attachment device configured to deliver and deploy the implantable anastomosis device to connect the graft vessel and the target vessel; and a single control operationally connected to both the cutting device and the graft vessel attachment device; wherein the cutting device and the graft vessel attachment device are mechanically linked to sequentially pass the cutting device and the graft vessel attachment device through a particular point in proximity to an anastomosis site in response to actuation of the single control."

In contrast, Nobis requires the actuation of two separate and distinct controls to pass the punch 600 and cartridge 200 through a particular point in proximity to an anastomosis site. "To cut the hole 905, the punch tip 602 is retracted by depressing the lever 620." (Nobis, *e.g.*, col. 9, lines 14-17; Figure 12). Next, "advancement of the knob cap 508...advances the cartridge 200...into the hole 905 thereby locking the cartridge 200 in the deploying position." (Nobis, e.g., col. 10, lines 1-13; Figures 14b, 15b). Thus, both the lever 620 and the knob cap 508--two independent controls--must be actuated "to sequentially pass the cutting device and the graft vessel attachment device through a particular point in proximity to an anastomosis site." This is contrary to the requirement of claim 12 that "the cutting device and the graft vessel attachment device are mechanically linked to sequentially pass the cutting device and the graft vessel attachment device through a particular point in proximity to an anastomosis site in response to actuation of the single control."

As a result, claim 12 is believed to be in condition for allowance. Claims 13-14 depend from claim 12, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

35 U.S.C. §103

MPEP 706.02(j) states:

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 1438 (Fed. Cir. 1991) (emphasis added).

Claims 1-2

As set forth above, Nobis fails to teach or suggest the limitations of amended claim 1 that require a "substantially hollow chamber and an introducer positioned at a distal end of the chamber and having a lumen open to the chamber, the introducer configured to substantially seal against the target vessel, whereby the chamber substantially maintains hemostasis...wherein the cutting device is movable to a position within the chamber after forming the opening in the target vessel."

Thus, the combination of Nobis and U.S. Pat. No. 6,605,098 to Vargas does not and cannot teach or suggest all of the limitations of amended claim 1. Consequently, claim 1 is believed to be in condition for allowance. Because claim 2 depends from amended claim 1, which is believed to be in condition for allowance, claim 2 is believed to be in condition for allowance as well under MPEP 608.01(n)(III).

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Claim 5

Because claim 5 depends from amended claim 3, which is believed to be in condition for allowance as described above, claim 5 is believed to be in condition for allowance as well under MPEP 608.01(n)(III).

REQUEST FOR ALLOWANCE

Allowance of the pending claims is respectfully solicited. Please contact the undersigned if there are any questions.

Respectfully submitted,

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